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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,655	06/20/2006	Paul J Bobrowski	PHMC0889-004	8863

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EXAMINER	
HOFFMAN, SUSAN COE	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
07/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@vclmlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,655	BOBROWSKI, PAUL J	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006 and 20 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-20 are currently pending.

Priority

2. According to USPTO data and the application data sheet filed by applicant this application is a 371 of PCT/US04/43760 which claimed priority to US Provisional Application Number 60/531,266. However, in the preliminary amendment filed November 20, 2006, applicant amended the first page of the specification to state that this application is a continuation-in-part of 10/676,459 which is a continuation-in-part of 09/655,598 which claimed priority to US Provisional Application Number 60/152,468. Clarification of the continuing data is needed.

Claim Objections

3. Claims 4 and 7 are objected to because of the following informalities: the claims do not end in a period. Appropriate correction is required.

4. Claim 17 is objected to because of the following informalities: the phrase "as well as" is a narrative phrase that is inconsistent with US practice. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 6-9, 12, 14, 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 3 is indefinite because is states that the liquid used is steam. Steam is a gas not a liquid; thus, to attempt to define steam as a liquid is in direct contrast to the actual definition of "steam." Claim 3 is also indefinite because it is unclear when the condensing step takes place during the process.

6. Claim 6 is indefinite because it refers to mechanical manipulation of the plant material in claim 1; however, claim 1 does not mention mechanical manipulation.

7. Claim 9 is indefinite because it states that the "liquid is depleted of its aqueous properties;" however, claim 1 does not require an aqueous liquid. Furthermore, claim 1 already states that the liquid is evaporated. Thus, it is unclear when the additional evaporation, heating, vacuum drying, or lyophilization step claimed in claim 9 would take place.

8. Claim 12 is indefinite because it is unclear what is encompassed by "compromises in fetal growth due to suppressed IGF levels."

9. Claim 14 is indefinite because it is unclear what ages are encompassed by "elderly."

10. Claim 19 is indefinite because it is unclear what ages are encompassed by "young" and "elderly."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 3, 4, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are drawn to a method of concentrating and extracting the polar constituent of plant material from the family Brassicaceae by exposing plant material to steam and condensing the steam into a liquid. Claim 7 specifies that the plant material is exposed to the steam through a porous structure and claim 8 specifies that the steam is condensed in a collector through temperature variation. According to the examples in the specification the condensed liquid contains the polar constituents of the plant material. However, this claimed procedure is steam distillation as described by Axtell ("Minor Oil Crops; Part III: Minor essential oil crops - section II: Distillation of essential oils" (1992) FAO Agricultural Services Bulletin, no. 94). The distillation apparatus described by Axtell contains a grid which holds the plant material above a boiler which provides steam (see Figure 3 and page 2). The steam moves through the plant material in the apparatus and then passes into a condenser where the steam is condensed into a liquid by cooling (see page 2). The condensed liquid contains the essential *oils* from plant material. Tellez (Phytochemistry (2002), vol. 61, pp. 149-155) also teaches that

steam distillation extracts the essential oils from Lepidium plants (see page 152, section 3.3). Oils are non-polar, not polar constituents. Thus, the claimed method and the method taught in the specification would not function to extract the polar constituents into the steam condensate because the steam condensate would contain the non-polar essential oil of the plant. This is demonstrated by the references. Therefore, since the claimed method would not function as claimed, an artisan could not reasonably be expected to carry out the invention as set forth in claims 3, 4, 7 and 8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 2, 5, 6, and 9-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheng (US 6,267,995).

This reference teaches a method of making a Lepidium extract. The extract contains concentrated polysaccharides and a low concentration of lipids, cellulose and lignin (see column 1, lines 32-36 and column 5, lines 16-18). The extract is made by cutting (i.e. chopping) the Lepdium into pieces, contacting the pieces with an aqueous solvent, separating the plant material from the aqueous phase and then evaporating the solvent from the aqueous phase to produce the

extract (see Examples 1 and 2). The reference also teaches that the solvent can be removed using lypophilization (see column 4, line 46).

The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng.

The teachings of this reference are discussed above. The reference teaches cutting the Lepidium into small pieces prior to extraction; however, the reference does not specifically teach using grinding, pureeing, or macerating. An artisan of ordinary skill would reasonably expect that these known method for reducing plant material to a smaller size would be useful in creating the small pieces of Lepidium taught by the reference. This reasonable expectation of success would motivate the artisan to modify Zheng to include grinding, pureeing, or macerating the Lepidium into granules, macerate, puree or powder as claimed.

The reference also teaches removing the liquid solvent using evaporation or lyophilization; however, it does not specifically teach using heating or vacuum drying. An artisan of ordinary skill would reasonably expect that heating or vacuum drying could be used to remove the solvent from the extract. This reasonable expectation would motivate the artisan to modify the method of Zheng to include using these methods to remove the solvent.

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655